REMARKS

Applicant expresses appreciation to the Examiner for conducting the recent interview with Applicant's representative. A summary of the interview is included within this document. Applicant has presented herein amendments to the claims discussed during the interview. A written response is also provided to reflect issues addressed throughout the interview. Pursuant to the interview discussion and the amendments submitted with this document, it is believed the outstanding rejections have been addressed, the cited art has been overcome and the application is in condition for allowance.

Pending Claims

Claims 17-20 and 23-34 remain pending. Claims 17 and 23 have been amended. Claims 35-44 have been canceled by way of the present amendment in an effort to expedite prosecution, but without prejudice to future prosecution of these or similar claims. Claims 1-16, 21 and 22 were previously canceled. No new matter has been added.

Claim Rejection under 35 U.S.C. § 103(a)

Claims 17-19, 23-24, 26, 28-37, and 39-41 have been rejected by the Examiner under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,370,653 to Cragg ("Cragg") in view of U.S. Patent No. 5,022,399 to Biegeleisen ("Biegeleisen"). In an effort to expedite prosecution, Claim 17 has been amended. Claim 17 is now directed to a method for permanently occluding a vein vessel wall. The claimed method involves damaging an extended portion of a vein by advancing an elongated intraluminal member into the vein, with the intraluminal member containing a portion configured to damage the inner vessel wall when performing a defined movement under the user's control, damaging the inner vessel wall by performing the defined movement, and injecting sclerosant onto the damaged inner vessel wall. The damage to the inner vessel wall comprises destruction and disruption of the endothelium that is sufficient to enhance the effect of the sclerosant, facilitate vein destruction, and increase the likelihood of permanent vein occlusion.

In rejecting Claim 17 under 35 U.S.C. § 103(a), the Examiner mischaracterized Cragg as disclosing a method for "moving the intraluminal member against the vein's endothelium at the treatment site to disrupt the endothelium and ensure it is damaged." A closer reading of Cragg reveals that Cragg actually teaches away from any damage-causing method. Cragg discloses a method for dissolving blood clots and restoring the flow of blood through blood vessels. Those of ordinary skill in the art understand that it would be highly advantageous to avoid damaging the

vessel wall when eliminating a blood clot. In fact, the portions of Cragg cited by the Examiner indicate that no damage is caused by using Cragg's device. Cragg specifically designed his device in order that "the risk of vessel wall rupture or pseudoneurism is decreased." *Cragg* at 4:8-9. This important feature of Cragg is further highlighted in the abstract where it is noted that the "bristles are sufficiently resilient and dimensioned for ease of introduction and mixing into the fibrin of the soft thrombus, *while not damaging the vessel wall.*" *Id.* at Abstract (emphasis added). Thus, Cragg's system, which is configured to dissolve blood clots while causing no damage to the vessel wall, is distinct from Applicant's system, which requires use of an intraluminal member "*configured to produce damage* to the inner vessel wall."

While Cragg acknowledges that the bristles of the apparatus "may cause minor abrasion and irritation," the apparatus and its disclosed method of use are designed purposefully to minimize vessel damage. *Cragg* at 9:10-11. Even inadvertent damage that may result from Cragg's device in the form of minor abrasions or irritation would be insufficient to: facilitate the destruction of the vein, enhance the effect of the sclerosant, and increase the likelihood of permanent vein occlusion as required by amended Claim 17. Furthermore, by simply noting the potential to inadvertently cause *minor* abrasions or irritation, Cragg is not teaching or suggesting the required step "wherein the damaging and injecting damages *an extended portion of the vein.*" Causing damage to an extended portion of the vein is especially advantageous, because it enhances the effect of the sclerosant and increases the likelihood of permanent occlusion. Thus, Cragg's failure to teach or suggest the infliction of damage to an extended portion of the vein creates a significant distinction between the two methods.

The damage-minimizing method in Cragg, which does not teach or suggest steps for creating user-controlled vessel damage, can be further distinguished from Applicant's claimed method, which requires a device "configured to produce damage to the inner vessel wall of the vein *under user control*," and which "damag[es] the inner vessel wall *by performing the defined movement* of the portion of the intraluminal member configured to produce damage."

The Examiner has recognized that "Cragg does not disclose injecting sclerosant into the vein," and cites Biegeleisen for teaching this additional step. However, there is no reason one of skill in the art would combine Cragg and Biegeleisen. As stated previously, Cragg was designed to dissolve blood clots in order to restore blood flow through treated veins. Even if unintentional damage to a vessel wall occurred while using the Cragg device, the user would not be motivated to

inject sclerosant at the damaged site, since the Cragg device is used to open vessels rather than permanently occlude them.

Moreover, secondary considerations "must always when present be considered en route to a determination of obviousness. Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (1983) *quoting In re Wood*, 599 F.2d 1032, 1036 (1979). Secondary considerations include long-felt but unsolved needs and failure by others to find an adequate solution. *Graham v. John Deere Co.*, 983 US 1 (1966). Here, a long-felt need for improved sclerotherapy exists, and others have continually failed to find such a treatment. Sclerotherapy has existed since 1851; however, the success rate for permanently occluding veins remains around 60% for this treatment. For years, modern sclerotherapy treatments have struggled to provide the right dose of sclerosant. As explained in ¶ 0012 of the present specification, if the dosage is too weak, no occlusion occurs; if the dosage is too strong, the sclerosant may flow into healthy veins near the treatment site and injure or occlude healthy vessels. These stated problems still exist with modern devices such as Biegeleisen. Thus, strong evidence suggests that at the time of invention, no solution to this problem was obvious to persons having ordinary skill in the art, even though catheter-based clot disruption techniques such as disclosed by Cragg have also been well-known for years.

Claims 18-20 and 23-34 ultimately depend from Claim 17; thus, these claims include all limitations of amended Claim 17. Accordingly, for at least the aforementioned reasons set forth in reference to independent Claim 17, Applicant respectfully submits that Claims 18-20 and 23-34 also define subject matter which is patentable over Cragg and Biegeleisen, taken individually or together.

When rejecting dependent Claims 18 and 19, the Examiner mischaracterized Cragg as disclosing "the step of scraping the intraluminal member against the endothelium." Similarly, in rejecting Claims 26 and 29, Cragg is mischaracterized as disclosing "scraping [by way of a rotating, motor-controlled intraluminal member] so that a portion of the intraluminal member engages the endothelium." *Id.* Nowhere within Cragg is the act of damaging the vein by scraping against or engaging the endothelium disclosed. Cragg discloses a "means for introducing the brush into contact with the soft obstruction [blood clot] and for repetitively passing the bristles of the brush through the soft obstruction so as to expose the fibrin of the obstruction." *Cragg* at Claim 1. This is again distinguished from Applicant's method, which leads to "destruction and disruption of the endothelium" and causes damage to "an extended portion of the vein" as required by Claim 17.

When rejecting dependent Claim 23, which contains all of the limitations delineated in claim 17 and adds the further limitation of "withdrawing the intraluminal member through the vein toward the access site *while* damaging the inner vessel wall and injecting sclerosant", the Examiner provided no additional argument, but rather relied on the mere assertion that it is unpatentable over Cragg in view of Biegeleisen. The Examiner does not provide any reference which teaches or suggests performing such actions concurrently.

Moreover, the Examiner rejected dependent Claim 20 as unpatentable over Cragg in view of Biegeleisen as applied to Claim 17, and further in view of U.S. Patent No. 6,048,332 to Duffy et al. ("Duffy"). Similarly, the Examiner rejected dependent Claim 27 as unpatentable over Cragg in view of Biegeleisen as applied to claim 26, and further in view of U.S. Patent No. 5,074,871 to Groshong ("Groshong"). The assertions that Claim 20 is unpatentable in view of Duffy and Claim 27 is unpatentable in view of Groshong are moot without first establishing that independent Claim 17 is obvious in light of Cragg and Biegeleisen. Moreover, the Examiner does not assert that Duffy or Groshong address the elements of Claim 17 that Cragg and Biegeleisen fail to teach or suggest. Accordingly, Applicant respectfully submits that the rejections of Claims 20 and 27 be withdrawn.

Finally, the prior art article cited by the Examiner, R.A. Williams, is similar to Biegeleisen in that both describe a method of injecting sclerosant into the vein at the treatment site in order to cause damage to the endothelium and treat varicosity. Neither reference teaches or suggests a method of damaging the vein prior to, or during, administration of the sclerosant. In rejecting Claims 17 and 35 as unpatentable over R.A. Williams in view of Cragg, the Examiner confused the direction of causation. Williams does not suggest that blood clots cause occlusion of the veins, but rather describes how improperly administered sclerotherapy can lead to blood clots. The potential development of blood clots is one of the many problems currently associated with sclerotherapy and an additional reason why the need for a better treatment, such as the treatment offered by Applicant, is so great.

The references of record do not render Applicant's claims obvious. The cited references do not provide all elements recited by Applicant's claims nor is there any suggestion for the combination of their various elements. At least for these reasons, and in light of the amendments made to the claims above, Applicant requests reconsideration and withdrawal of the Examiner's rejections.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Respectfully submitted,

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